

Britain expected to become first country to approve challenge trials for COVID-19 vaccine candidate

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LONDON

PUBLISHED SEPTEMBER 29, 2020

UPDATED SEPTEMBER 30, 2020

PUBLISHED SEPTEMBER 29, 2020

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Samples from volunteers are handled in the laboratory at Imperial College, in London, on July 30, 2020.

KIRSTY WIGGLESWORTH/THE ASSOCIATED PRESS

The pandemic has prompted a lot of self-sacrifice, but few people have been willing to go as far as British teenager Alastair Fraser-Urquhart.

Mr. Fraser-Urquhart, 18, has volunteered to be infected with COVID-19 to help speed up the development of a vaccine. He's part of a non-profit group called 1 Day Sooner, which is pushing countries around the world, including Canada, to approve human challenge trials. The group argues that such trials – which involve vaccinating volunteers and then infecting them with the virus – can shave months off the time it takes to produce a vaccine.

“The challenge trials have just got the potential to do so much good,” Mr. Fraser-Urquhart said from his home in Stoke-on-Trent. “To me, it's just a common sense idea.”

The group's efforts appear to be paying off. This week, Britain is expected to become the first country to approve challenge trials for a COVID-19 vaccine candidate. The vaccine is being developed by Imperial College, which has formed a social enterprise to manufacture it, and the trials will be conducted in a special facility in London. Volunteers are likely to spend about two months in the challenge unit, where they will receive doses of the vaccine as well as the virus.

It's a controversial move, and some researchers point to the ethical ramifications of potentially making people sick. Challenge trials have been used in the development of vaccines for the flu, cholera, typhoid and malaria, but COVID-19 is not fully understood and there is no known cure. That means researchers won't have a “rescue treatment” if volunteers become seriously ill.

Normally during late-stage trials, known as Phase 3, volunteers are inoculated with a vaccine candidate and then return to their normal lives. Researchers wait to see how many become infected – and how severely – and compare the results with a control group, which received a placebo. The entire process can take months and often involves as many as 30,000 volunteers. Currently there are nine vaccines in Phase 3 trials.

Challenge trials expedite that process by infecting volunteers just a couple of weeks after they've been vaccinated. That shortens the time needed to see whether the vaccine works and to check the results against a control group. It also means researchers don't need as many volunteers.

Eleanor Riley, an immunologist at Edinburgh University, said this summer that challenge trials “should be incapable of causing severe illness in healthy individuals – or there should be a highly effective drug to clear the infection.” That criteria has not been met, she added. Other scientists have questioned whether such trials will actually speed up vaccine development, given how long it will take to put safety measures in place.

Proponents of challenge trials argue that the risks can be minimized by using young adults as volunteers, as they appear to be less prone to severe forms of the illness. They also say the world will need more than one COVID-19 vaccine and that conventional trials will take too long.

“Time is lives,” said Dominic Wilkinson, a professor of medical ethics at the University of Oxford. “If we identify a vaccine one week or one month sooner, that will potentially save tens of thousands of lives, and the reality is we’re looking at needing 12 billion vaccine doses. Because of that, we’ll need more than one vaccine.”

Dr. Wilkinson added that there is “a strong ethical argument in favour of facilitating these trials in order to identify as quickly as possible the most effective vaccine.”

Alexandre Rodgers is among the 1,600 Canadians who have signed up with 1 Day Sooner to be a trial volunteer. Mr. Rodgers, 27, has also helped launch a petition calling on Ottawa to clear the way for challenge trials in Canada.

“To me, the smaller risk that I face is definitely worth the potential benefits for those who are disproportionately affected by the COVID pandemic,” he said from his home in Sherbrooke, Que. He’s hopeful the Canadian government will follow Britain’s lead and work with other countries.

“I’m sure there are international agreements that can be struck to share challenge trials or have challenge units in multiple countries,” he said. “It is valuable to have diverse populations involved.”

Conor Barnes, who lives in Kelowna, B.C., has also signed up to be a volunteer and knows he could become ill. “What if I have trouble breathing forever?” he asked. “You have to know that going in. If I can take on that risk, and prevent thousands of others having to take it on, then that’s the right thing to do.”

Health Canada has yet to approve a challenge trial, but the agency has developed “rapid guidance” for COVID-19 vaccine trials. The guidelines note that challenge trials “are ethically

complex” but could answer a number of key questions about a vaccine candidate. Any challenge trial would “have to be carefully navigated with Research Ethics Boards and the federal regulator,” the guidelines say. The trial would also have to follow criteria laid out by the World Health Organization.

The WHO has said that any challenge trial must be closely monitored and should only involve volunteers between the ages of 18 and 25. It added that all trials should take place in secure facilities to avoid spreading the virus.

But a WHO scientific advisory group also raised several concerns about such trials. Almost half the group’s members – nine out of 19 – felt these trials should not begin until there was a rescue treatment. And more than half the panel – 11 out of 19 – said that testing a vaccine solely on young adults raised questions about whether it would work on elderly people or other vulnerable groups.

Mr. Fraser-Urquhart doesn’t want to wait any longer. He’s hoping to be the first in line for the challenge trial in London. “I think the real problem is not that people don’t want to do it, but no one wants to be the first,” he said. “So once it’s started, I can’t imagine people saying: We don’t want a challenge trial.”

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